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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/682,647

10/08/2003

Jonathan D. Bloom

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FITZPATRICK CELLA HARPER & SCINTO  
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NEW YORK, NY 10112

EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/682,647

Applicant(s)

BLOOM ET AL.

Examiner

Yevgeny Valenrod

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10, 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 11-14 and 17-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-18 are pending

Rejections of claims 1 and 15 are withdrawn in view of applicants' remarks.

Objection of claims 2-14 and 16 is withdrawn.

Rejection under 35 USC 102(b) of claims 11, 12 and 17 is maintained and is made final.

Rejection of claims 11-14, 17 and 18 under 35 USC 103(a) is maintained and is made final.

Text of the rejections in the office action mailed on 6/16/06 that are maintained is repeated below, followed by Examiners' reply to applicants' remarks.

#### ***Rejections 35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 12, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al (J. Med. Chem. 2001 44 3187). On page 3188 column 2 structure 17, Wright teaches 2-[[N-(3-bromophenyl)glycyl]amino}benzoic acid and 2-[[N-(3,4-dichlorophenyl)glycyl]amino}benzoic acid which are found in the generic structure of claims 11, and 17 and is specifically listed in claim 12.

Applicants' remarks

Applicant argues that: 1) Wright et al do not disclose the compounds being useful for treatment of hepatitis, 2) the compounds disclosed by Wright et al are not in a composition with a pharmaceutically acceptable carrier.

Examiners' response

The compounds disclosed by Wright are the same as the ones claimed by the applicant. On page 3192, paragraph 3 (titled step 2), lines 7-12, Wright describe a method of preparing compound 17. They describe that after the reaction to form compound 17 is complete the mixture is extracted with dichloromethane and the aqueous phase is treated to recover the product. The product is recovered from the aqueous phase. Hence, before the recovery, compound 17 was in water, which is a pharmaceutically acceptable carrier.

It is well settled that the intended use of a composition or product (e.g. as a cosmetic composition) will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount as instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d, 1647.

***Rejection 35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious

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at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-14, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bierer et al (US 5,741,926).

The instant application claims pharmaceutical compositions comprising compounds as described by formulas of independent claims 11 or 17, and their dependent claims 12-13 and 18.

*Scope of prior art*

Bierer et al. teach a general structure of Formula III that encompasses the compounds included in claims 11-14, 17 and 18 of the instant application.

*Ascertaining the difference between prior art and the instant application*

Although the structure of formula III taught by Bierer et al. encompasses the specific compounds of the instant application, it does not specifically list the same compounds as are recited in claims 12-13 and claim 18.

*Obviousness*

The generic structure of formula III teaches the instant claims with sufficient particularity that the compounds of the instant invention would have been prima facie obvious. The said particularity arises from structural similarities such as the 2-(((phenyl)amino)acetyl)aminobenzoic acid structural core and the optional multiple substitutions with various halogens which are present in the specific examples provided by Bierer et al (see column, 11 line 40 – column 12 line 16).

Applicants' remarks

Applicant argues that

1) US Patent 5,741,926 ('926) does not teach the compound of instant invention and that the compound disclosed in '926 does not have important feature of having a COOH, COOCH<sub>3</sub> or 5-tetrazolyl group at the ortho position of the benzene ring.

2) '926 does not teach or suggest that the disclosed compounds are potent inhibitors of HCV polymerase or possess any anti-hepatitis activity.

Examiners' response

In column 11, line 43, '926 disclose compound (AC). Applicant has described the substitution at the ortho position as an important structural feature of the instantly claimed compounds. Compound (AC) has the COOH functionality in the ortho position. Although applicant there should be additional substituents at the 4 or 5 positions, claims 11 and 17 have identified H as being a possible identity of substituents G, G<sub>1</sub> and G<sub>2</sub>. Compound (AC) meets that limitation as well. In addition, the examples provided in applicants' remarks display activity for inhibition of CHV polymerase and do not have a substituent other than H in the 4 or 5 position. The compounds described in '926 are also described as pharmaceutical compositions (column 12, lines 23-28). The intended use of a composition does not further limit the composition.

***Allowable subject matter***

Claims 1-10 and 15-16 are allowed. The closest, already cited in this office action teaches the compounds of the instant invention. However, the art does not teach or suggest a method of treating hepatitis C by administering the said compounds. There is no suggestion that would motivate one of ordinary skill in the art to administer the compounds of '926 or of Wright et al. in order to treat HVC.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***


Claims 1-10 and 15-16 are allowed.

Claims 11-14 and 17-18 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

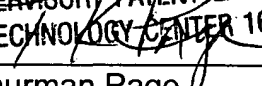
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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